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Six-Year Outcomes Following Endovascular Therapy with Nitinol Stenting for TransAtlantic Inter-Society Consensus C-D Lesions in the Femoro-popliteal Segment

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Background: TransAtlantic Inter-Society Consensus (TASC) guideline recommended femoro-popliteal (FP) bypass as standard treatment for TASC C-D lesions. Although several studies have identified 5-year primary patency for FP bypass of around 70%, complication rate is high compared with endovascular therapy (EVT). Accordingly, EVT with nitinol stent implantation has been widely used for FP lesion. However, long-term results of stenting, especially for TASC C-D lesions, remain unclear. Thus, this study examined long-term outcomes of nitinol stent implantation for TASC C-D FP lesions, factors associated with the restenosis and risk stratification according to predictors.

Methods: Between December 2003 and December 2009, 381 patients with 471 TASC C-D FP lesions (mean age 72.4 years; 67.5% male) underwent nitinol stent implantation. Restenosis was defined either by duplex ultrasound or angiography. Patency was analyzed by Kaplan-Meier estimation. Predictors for restenosis were determined by Cox multivariate regression analysis, and primary patency rates were compared between low or high risk groups that were created based on number of predictors present.

Results: Mean lesion length was 230±65mm. At 6 years, the primary and secondary patency rate and amputation-free survival rate was 51%, 77% and 72.7%, respectively. By Cox multivariate regression analysis, female gender (hazard ratio [HR] 1.51; 95% confidence interval [CI] 1.09-2.10; P=0.014), diabetes (HR 1.73; 95% CI 1.15-2.59; P<0.01), claudicator (HR 1.73; 95% CI 1.15-2.59; P<0.01), without SMART stent implantation (HR 1.66; 95% CI 1.17-2.35; P<0.01), and reference vessel diameter < 6mm (HR 1.49; 95% CI 1.07-2.99; P=0.017) were the predictors for restenosis. Primary patency in the low-risk group (number of risk factors 0-2) and high-risk group (3-5) at 6 years was 60.0% vs. 35.4%, p<0.0001, respectively.

Conclusion: EVT using nitinol stents yielded acceptable outcomes out to 6 years in TASC C-D FP lesions. Revascularization strategy for TASC C-D lesions should be chosen according to risk stratification.

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WITHDRAWN

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COMPLIANCE 360°: A Prospective, Randomized, Multicenter Trial Comparing Balloon Angioplasty to Diamondback 360° Orbital Atherectomy System in Calcified Femoropopliteal Disease

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Background: Stent placement in the distal superficial femoral and popliteal arteries is associated with increased risk of stent fracture and restenosis. Lesion calcification is predictive of vessel dissection and recoil after PTA. This study examines whether the Diamondback 360° Orbital Atherectomy System (DB360) (Cardiovascular Systems, Inc., St. Paul, MN), by changing the compliance of calcified femoropopliteal (FP) lesions through the mechanism of differential sanding, diminishes the frequency of adjunctive (bailout) stenting without sacrificing intermediate term patency.

Methods: 50 symptomatic patients (66 lesions) from 10 sites with calcified FP lesions of ≥70% were equally randomized to PTA alone vs. DB360 followed by low pressure PTA up to 4 atmospheres (atm) with the endpoint of residual stenosis ≤30%. Lesions failing to achieve this endpoint with the prescribed therapy were then treated with bailout stenting. Freedom from target lesion revascularization (TLR), including the need for bailout stenting, or restenosis defined as a peak systolic velocity ratio of ≥2.5 on duplex study at 6 months, was the primary endpoint.

Results: 92.1% of 38 lesions in the DB360 arm and 21.4% of 28 lesions in the PTA arm (p<0.0001) met the angiographic endpoint after primary therapy. 2 of 25 pts in the DB360 arm vs. 21 of 25 pts in the PTA arm required bailout stenting (p<0.0001). Mean maximum balloon pressure (a measure of lesion compliance) in the DB360 arm was 3.9 atm vs. 8.5 atm in the PTA arm (p<0.0001). At 6 months, 4 pts in the DB360 arm vs. 3 pts in the PTA arm had restenosis (p=NS); 2 of 3 in the PTA arm were in-stent. Freedom from TLR or restenosis at 6 months was 72.7% (16 of 22 pts) in the DB360 arm and 8.3% (2 of 24 pts) in the PTA arm (p<0.0001).

Conclusion: Compared to PTA alone, orbital atherectomy with low pressure PTA leads to better luminal gain by improving lesion compliance with less need for adjunctive stenting when treating calcified FP lesions. Patency at 6 months is comparable to PTA with a provisional stent strategy.

TCT-94

Results of the ALSTER hypertension registry: first experience with renal denervation

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Background: Renal denervation was found to be effective in drug-resistant hypertension. Here we describe the results of the first 31 patients treated outside the study criteria regarding reduction of drug intake and effectiveness.

Methods: Between May 2010 and January 2011 31 patients were treated with the Ardian simplicity system. These patients were followed for 6 months with repetitive diabetes and hypertension monitoring. No side-effects related to the ablation were documented. Patients were required to have at least 3 medications on board to be eligible; systolic blood press was measured at least once > 160 mmHg. In addition, echo criteria regarding diastolic dysfunction, HbA1c as a measure of glycemia control as well as renal function were closely monitored.

Results: After a 6 months follow up, 65% of patients responded to the therapy with either a measurable drop in blood pressure measured at the outpatient follow up visit 3 months after the procedure (35%) and/or less dyspnoe on exertion. 16% of patients reduced their medication in part due to dizziness with the newly decreased blood pressure. No effect on HbA1c was detected in this cohort; HbA1 was > 5.9% in 55% of patients. No measurable effect on diastolic dysfunction was found during the above mentioned follow up period of 6 months.

Conclusion: Renal denervation was found safe and partially effective; we have since altered our system. Re-evaluating the patients who did not respond to treatment suggest duration of hypertensive treatment to be an independent predictor.

TCT-95

Acute And Long-term Follow-up Results Of Renal Angioplasty In Takayasu Arteritis

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Background: Takayasu arteritis frequently presents with hypertension in young adults. Stenosis of one or both renal arteries is present in most of them and angioplasty of these lesions is expected to control hypertension and control renal damage. We present the acute and long term results of renal angioplasty done for the last 8 years in our hospital.

Methods: All cases of Takayasu arteritis, diagnosed basing on criteria suggested by Ishikawa, who underwent percutaneous transluminal renal angioplasty (PTRA) in our hospital from 2003 were followed up clinically and by a renal Doppler in all cases at all visits. A cine renal- angiogram was advised at 6 months and 18 month visit. During 2003 to 2008, we performed renal angioplasty in 85 lesions (76 patients; 54 females; age range 24 to 47 years; mean 29.5±5.65 years). Unilateral lesions were seen in 67 patients and rest had one lesion in each kidney. Ostial lesions constituted % (29/85) of the cases. Of them 64 cases who had at least 18 months follow-up data were included for analysis.

Results: Results: Technical success rate for the first PTRA was 90.5% (77/85) lesions. Of the 8 failure cases one with bilateral lesions was sent for emergency surgery due to renal artery rupture following PTRA and 5 underwent surgical revascularization. Of the ostial lesions technical success rate was 68.9 % (21/29). There was no mortality in any case. On a mean follow up of 22.5±8.55 months 19 of 64 cases {23 of 66 lesions (34.8%)} developed restenosis and 17 of them were successfully redilated. There was death of one patient with bilateral lesions due to CRF. Cure of hypertension (BP <140/90 mmHg without need for medication) and improvement (BP<140/90 mmHg with same or reduced number of medications) was achieved in 25/64(39%) and 24/64(37.5%) respectively. Of the 25 cases with raised serum creatinine 17/25 (68%) had shown a fall in their values in follow-up (mean 1.91± 1.05mg to 1.3±0.76 mg; p<0.005)

Conclusion: PTRA is technically feasible with acceptable acute results. Ostial lesions are more difficult to be dilated. The restenosis is seen in about one-third of the cases after successful procedure which can be redilated. Control of hypertension and renal dysfunction is achieved in a significant number of cases.

TCT-96

Impact of Preexisting Cerebral Ischemia Detected by Magnetic Resonance Imaging and Angiography on Clinical Outcomes After Coronary Artery Bypass Graft in Patients Without History of Stroke

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Background: Limited data existed for long-term clinical outcomes of asymptomatic brain ischemia after coronary artery bypass grafting (CABG). We sought to assess the impact of preexisting ischemia detected by brain magnetic resonance imaging and angiography (MRA) on clinical outcomes after CABG.

Methods: Between Jan. 2003 and May 2009, 3,071 patients underwent CABG in Asan Medical Center. Preoperative brain MRA was performed in 2,417 patients. Patients